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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,912

11/29/2006

James E. Polli

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09/28/2011

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RESTON, VA 20190

EXAMINER

FUELLING, MICHAEL

ART UNIT

PAPER NUMBER

3626

MAIL DATE

DELIVERY MODE

09/28/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,912	Applicant(s) POLLI ET AL.	
	Examiner MICHAEL FUELLING	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-3,5-10 and 33-35 is/are pending in the application.
- 5a) Of the above claim(s) 1,2,5-10 and 33-35 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 3 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

This is a Final office action for Application Number 10/572,912 filed 3/21/2006.

Claims 1-10 currently are pending.

Claims 1-3 and 5-10 have been amended.

Claim 4 has been cancelled.

Claims 33-35 are new.

Claims 1, 2, 5-10 and 33-35 are deemed withdrawn.

Claim 3 has been examined.

Notice to Applicant

The objection to the specification also will be held in abeyance, and the 35 USC 101 claim rejection is withdrawn.

Election/Restrictions

Newly submitted claims 33-35 and amended claims 1, 2 and 5-10 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally elected claims did not recite the tag which has been added.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1, 2, 5-10 and 33-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The step appears to be observable and verifiable. It also is being interpreted that the product is an object or substance.

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Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over an embodiment Julia et al., US Patent No. 6,907,351 (Julia) in view of the background of Julia.

The claim recites “the source” (emphasis added). It is being construed by the examiner that at least one source is known.

The claim recites “a plurality” in both the preamble and at the end of the claim, but recites “the plurality” in the middle of the claim. It is being construed by the examiner that this is the same plurality.

The claim recites “the production batch” (emphasis added). It is being construed by the examiner that “among different batches ... produced” a selection is made.

So, it is being construed by the examiner that the single step method is capable of identifying the selected batch among the plurality of batches produced by the at least one known source.

The claim was amended to recite “wherein intentional variation” (addition shown). It is being construed by the examiner that applicants intended “the intentional variation” as it is understood that this variation is made by the step of intentionally varying.

The claim also was amended to recite an adverb combination: “that intentionally detectably differs” (addition shown). It is being construed by the examiner that detectably modifies the verb differs, and that intentionally modifies detectably, but that applicants do not intend to actually add another step, such as a detecting step since the claim was amended to

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recite “comprising the step of” (addition shown). So, it is being construed by the examiner that the product is capable of undergoing an intentional detecting step.

In Julia, it is the customer / manufacturer (see Abstract copied below) who varies the contents of the product while the claimed method is irrespective of who varies the components.

A method and system for predicting the content level of components in materials based on the response of the materials to near infrared radiation. One embodiment comprises electronically receiving a near infrared reflectance spectrum of a material from a customer, predicting the content level of a component in the material based on the spectrum, and electronically reporting the prediction to the customer. Another embodiment includes the exchange of the customer request and prediction report on a Web site or by electronic mail. Other embodiments include the prediction reports, and uses of the predictions, for example in quality control and toxicity evaluation.

Julia also discloses the product can be of a wide array, *e.g.*, food or pharmaceuticals (C4, L10-15).

In particular, Julia discloses:

- intentionally varying an amount of at least one of the one or more inactive ingredients (C4, L28 “inactive ingredients) among different pharmaceutical products produced (Abstract “predicting content level of components in materials” and C4, L10-15 pharmaceuticals),
- wherein intentional variation in the amount of, at least one of the one or more inactive ingredients in a product results in an NIR spectrum for the product that intentionally detectably differs from an NIR spectrum for a different product among the plurality of products (Abstract using infrared **120**).

To the extent that it can be shown that the disclosed embodiment(s) of Julia are being applied to continuous manufacturing, rather than batch production, such that Julia might not appear to expressly disclose the feature of:

- thereby identifying the source of the lot / batch / product of the pharmaceutical product from among a plurality of lots / batches / products of the pharmaceutical product.

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Julia's background teaches that batch production is an old and well known product manufacturing technique (C1, L44 batches).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Julia's NIR product identification method to apply it to distinguishing between different batches of pharmaceutical products, and the results would have been predictable, because it is the application of a known technique to a known method.

One would have been motivated to make the combination because it would help to improve monitoring the contents of the products.

Response to Arguments

Applicants' arguments have been fully considered, but they are not persuasive.

(A) Applicants argue that Julia allegedly does not teach varying anything. The examiner maintains that Julia fairly discloses, teaches or suggests varying active and inactive ingredients. Julia would have no reason to use NIR if the composition remained constant or fixed over time.

(B) Applicants appear to be arguing that Julia allegedly does not fairly disclose, teach or suggest the *intentional* variation of inactive ingredients. However, there is no evidence that the variations made in Julia are accidental or mere happenstance. On the contrary, the variations made in Julia are the result of process control (C1, L44 batches).

(C) Applicants' arguments also are not commensurate with the scope of the claims. For example, applicants' claim is not directed to detection of counterfeiting as applicants contend. Applicants' claim recites "the source." Applicants' claim does not recite some unauthorized and/or unknown source.

(D) Applicants criticize the use of the background of Julia as the secondary teaching for the obviousness rejection. It has been held that prior art reference must be considered in its

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entirety. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure.

Buchanan teaches that the concept of intentionally varying inactive ingredients in pharmaceuticals to uniquely identify them by their chemical formulation using NIR [0075-0076].

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL FUELLING whose telephone number is (571)270-1367. The examiner can normally be reached on Monday - Friday, 8:30 am - 5 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Morgan can be reached on (571)272-6773. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. F./

Examiner, Art Unit 3626